Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA

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This document supersedes "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" dated December 19, 2002.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments with respect to absorbable polydioxanone surgical suture (21 CFR 878.4840), please refer to the exact title of this guidance document. When submitting comments with respect to sutures **other than** the absorbable polydioxanone surgical suture, please refer to Docket No. 02D-0289. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/1387.pdf, or to receive this document by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (**1387**) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document was developed as a special control guidance to support the reclassification of the absorbable polydioxanone surgical (PDS) suture into class II. It was also developed as the special control for eight other surgical suture devices previously classified into class II. All nine surgical sutures are listed in **Table 1.** The devices are intended for use in soft tissue approximation, including use in ophthalmic surgery and in pediatric cardiovascular surgery where tissue growth is expected to occur.

On December 19, 2002, this guidance document was issued in conjunction with a Federal Register notice announcing the reclassification of the absorbable PDS suture.

In the same December 19, 2002 issue of the Federal Register, FDA proposed amending the classification regulations for the eight other surgical suture devices previously classified into class II to designate this guidance document as the special control for each suture device. Now, this guidance document is updated and re-issued in conjunction with a Federal Register notice announcing the designation of special controls for these eight surgical suture devices.

This 2003 guidance document supersedes “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA” dated December 19, 2002.

Following the effective date of this final reclassification rule, any firm submitting a premarket notification (510(k)) for a surgical suture will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of these surgical suture devices. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with surgical suture devices identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.85).

This special control guidance document identifies the classification regulations and product codes for the surgical sutures to which it applies (refer to Section 4 – **Scope)**. In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these generic suture types and lead to a timely 510(k) review and clearance. This document supplements other agency documents regarding the specific content requirements of a 510(k) submission. You should also refer to 21 CFR 807.87 and other agency documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, http://www.fda.gov/cdrh/manual/510kprt1.html.

As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, http://www.fda.gov/cdrh/ode/parad510.html, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a special controls guidance document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues**" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this guidance document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this Class II Special Controls Guidance Document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 11 for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

The summary report should contain:

- Description of the device and its intended use. We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to Section 5 for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[1]

- Description of device design requirements.

- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device that FDA has identified.)

[1] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

- Discussion of the device characteristics that address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.

- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 7-10 of this Class II Special Controls Guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[2] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

- If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.[3] Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information, see FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

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[2] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria, and thus differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[3] See Required Elements for a Declaration of Conformity to a Recognized Standard (SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS), http://www.fda.gov/cdrh/ode/reqrecstand.html.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a 510(k) for a surgical suture.

4. Scope

The scope of this guidance document is limited to the following devices listed in **Table 1**.

Table 1: Designated Surgical Sutures

Suture Name	Regulation	Procode
Absorbable Polydioxanone Surgical (PDS) Suture	21 CFR §878.4840	NEW
Absorbable Poly(glycolide/L-lactide) Surgical Suture	21 CFR §878.4493	GAM
Absorbable Gut Suture	21 CFR §878.4830	GAL
Nonabsorbable Poly(Ethylene Terephthalate) Suture	21 CFR §878.5000	GAT
Nonabsorbable Polypropylene Surgical Suture	21 CFR §878.5010	GAW
Nonabsorbable Polyamide Surgical Suture	21 CFR §878.5020	GAR
Natural Nonabsorbable Silk Surgical Suture	21 CFR §878.5030	GAP
Stainless Steel Surgical Suture	21 CFR §878.4495	GAQ
Nonabsorbable Expanded Polytetrafluoroethylene (ePTFE) Surgical Suture	21 CFR §878.5035	NBY

5. Device Description

We recommend that you identify your suture, by regulation and product code (see Section 4 - **Scope**), and include the following information:

- the identity and percentages of all materials (including coatings and additives)
- the sizes of sutures using the size system identified in the currently recognized United States Pharmacopoeia (USP)
- the listing as described in 21 CFR 70.5(c) that identifies the color additive, if used. All sutures must meet the requirements of 21 CFR 70.5(c) regarding the use of color additives in sutures. For color additives not already approved for use in your suture material, you must obtain approval of a color additive petition from the Center for Food Safety and Applied Nutrition, in accordance with 21 CFR Part 71, prior to submission of a 510(k).

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the surgical suture devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. Your 510(k) should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	**Recommended mitigation measures**
Improper selection and use	Sections 10 and 11
Suture breakage	Sections 9 and 10
Adverse tissue reaction	Sections 7 and 10
Infection	Sections 8 and 10

7. Biocompatibility

FDA recommends that you conduct biocompatibility testing as described in the FDA-modified **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**, http://www.fda.gov/cdrh/g951.html. You should conduct testing appropriate to the body contact and contact duration in your indications for use, typically for sutures, the testing described in Parts 5 (*in vitro* cytotoxicity) and 10 (irritation and sensitization) of ISO-10993.

8. Sterility

We recommend that you provide sterilization information for the finished suture in accordance with the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/361.html.

9. Physical/Performance Characteristics

We recommend that all surgical sutures conform to the monographs and sections listed below of the currently FDA-recognized edition of the USP. We recommend that you conduct all testing on the sterilized suture in finished form (e.g., needled, in reels) as per the Monograph for Nonabsorbable Sutures or as per the Monograph for Absorbable Sutures. The testing in these monographs include:

- Sutures - Diameter <861>
- Sutures - Needle Attachment <871>

- Tensile Strength <881>.

Resorption Profile

For all absorbable sutures, we recommend that you demonstrate the resorption profile of the final sterilized suture *in vivo* or *in vitro*. The resorption profile should contain a chart, table, or graph that illustrates the residual tensile strength of the suture for a clinically significant period of time. The length of time considered clinically significant depends on the suture's intended use. We recommend that you show that the resorption profile is consistent with the intended use. Examples of intended uses of absorbable surgical sutures are short-term and long-term approximation of tissue.

The numbers of sutures tested should be sufficient to demonstrate that the tensile strength retention of the surgical suture will be consistent. This usually consists of testing at least the largest and smallest sizes of your suture, as well as the sizes in between, skipping no more than two size differences between sizes tested. For example, if you intend to market all suture sizes from 7 to 7-0, we recommend that you test the sizes 7, 4, 1, 2-0, 5-0, and 7-0 for tensile strength retention.

10. Clinical Studies

In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997, the agency will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most surgical suture devices, FDA may recommend that you collect clinical data for a surgical suture device with:

- a formulation dissimilar from formulations previously cleared under a 510(k);
- a new technology, i.e., technology different from that used in legally marketed surgical suture devices; or
- indications for use dissimilar from indications for use of sutures of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. The Plastic and Reconstructive Surgery Devices Branch is available to discuss any clinical testing with you before you initiate studies.

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications reviewed in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with the regulations governing institutional review boards (21 CFR 56) and informed consent (21 CFR 50).

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the IDE regulation (21 CFR 812). FDA has determined that sutures addressed by this guidance document are significant risk devices as defined in 21 CFR 812.3(m)(4).[4] In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with Parts 50 and 56.

11. Labeling

The 510(k) should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).[5]

Reference to USP

If your suture meets all requirements established by the USP for Non-absorbable Surgical Sutures, Absorbable Surgical Sutures, or Synthetic Absorbable Surgical Sutures, we recommend that you state this in the labeling.

FDA permits reference to USP only when all USP specifications are met. If one or more USP specifications are not met, you should not reference USP in the trade or generic name. If your suture does not meet all USP requirements, the labeling should clearly state that suture is non-USP and describe the respects in which it is non-USP.

Description

The description should:

- state whether the suture is absorbable or non-absorbable;
- give the material composition or biological (species and tissue) sources; and
- list any packing fluids, dyes, or coatings.

Indications

The indications should list the kinds of surgery, sites in the body, and, in some instances, the patient populations where the suture is intended to be used.

[4] Refer to Blue Book Memorandum entitled "SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES" at http://www.fda.gov/cdrh/d861.html.

[5] Although final labeling is not required for 510(k) clearance, final labeling must also comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

Performance

For absorbable sutures, the labeling should describe:

- how the suture is absorbed and the rate of absorption;
- how tensile strength changes over time; and
- when absorption is usually complete.

For non-absorbable sutures, the labeling should describe whether any significant loss of tensile strength occurs over time.

In addition, your labeling should state "For Single Use Only."

Contraindications

You should list the contraindications appropriate to your suture. Contraindications should include any surgery types, body sites, or patient populations where evidence demonstrates that the suture should not be used.

Warnings

You should list the warnings appropriate to your suture. A complete warning is a statement that not only describes the serious adverse reactions or potential safety hazards associated with the device but also includes the possible consequence. As an example, consider the warning, "Avoid prolonged contact with urine or bile." A better written or complete warning would include the consequence and, thus, state "Prolonged contact with urine or bile may result in calculus formation."

Precautions

You should list the precautions appropriate to your suture. A precaution is a statement that informs users of the measures they should take to avoid adverse events or potential safety hazards while using the device. For example, "Avoid crushing or crimping the suture when handling it with forceps or needle holders. Crushing or crimping may adversely affect the tensile strength or absorption rate of the suture." As with warnings, precautions should include the consequence.

Adverse Reactions

You should identify adverse reactions associated with the use of the suture. You should list separately adverse reactions observed with all sutures versus those adverse reactions observed only with your suture type.

How Supplied

You should state whether your suture is supplied sterile, in cut lengths or ligating reels, and affixed to needles or non-needled. You should also list the sizes and per unit packaging (e.g., one-, two-, and three- dozen box) available.